

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

ADVERIO PHARMA GMBH, BAYER  
AG, and BAYER HEALTHCARE  
PHARMACEUTICALS INC.,

Plaintiffs,

v.

ALEMBIC PHARMACEUTICALS  
LIMITED, ALEMBIC GLOBAL  
HOLDING SA, and ALEMBIC  
PHARMACEUTICALS, INC.,

Defendants.

C.A. No. 2:23-cv-01285-ES-JBC

C.A. No. 2:22-cv-06104-ES-JBC

**STIPULATED PROTECTIVE ORDER**

Whereas this is a Hatch-Waxman case involving a patent dispute relating to the drug riociguat;

Whereas discovery in this action may involve the disclosure of certain documents, things and information (including electronically stored information) in the possession, custody or control of a party or a non-party that constitute or contain trade secrets or other confidential research, development, manufacture, regulatory, financial, marketing or other competitive information within the meaning of Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure or contain information involving privacy interests of individuals; and

Whereas the parties have in good faith conferred and have agreed upon the terms of a Protective Order and for good cause shown; therefore

The parties stipulate, pursuant to Rule 26(c) of the Federal Rules of Civil Procedure, subject to the approval of the Court, to the following Protective Order:

**1. Scope of Protection.**

1.1 This Protective Order shall govern any record of information, designated pursuant to ¶ 3 of this Protective Order, produced in this action, including, without limitation, all designated deposition testimony, all designated testimony taken at a hearing or other proceeding, all designated interrogatory answers, documents and other discovery materials, whether produced informally or in response to interrogatories, requests for admissions, requests for production of documents or other formal methods of discovery.

1.2 This Protective Order shall also govern any designated record of information produced, exchanged, or served in this action pursuant to required disclosures under any federal procedural rule or District of New Jersey Local Rules, and any supplementary disclosures thereto.

1.3 This Protective Order shall apply to the parties and any non-party from whom discovery may be sought and who desires the protection of this Protective Order. If an additional party unrelated to one of the plaintiffs or one of the defendants (or a successor in interest to any of them) joins or is joined in this action, the newly joined party shall not have access to documents or other information produced under protection of this Protective Order until the parties agree to a supplemental protective order or agree to be bound by the terms of this Protective Order.

1.4. The Access and Non-Disclosure Agreement dated May 2023 between the parties is replaced by the terms of this Protective Order.

**2. Definitions.**

2.1 As used herein, the terms “CONFIDENTIAL” and “CONFIDENTIAL INFORMATION” (which are used herein interchangeably and are synonymous with one another) mean any information used by a party or non-party in or pertaining to its business, which information is not publicly known, including any form of trade secret or other confidential

research, development, or commercial information within the meaning of Fed. R. Civ. P. 26(c)(1)(G). To the extent a party agrees to produce this information, information shall be designated CONFIDENTIAL INFORMATION if the information constitutes (i) any approved or unapproved (whether pending or not yet filed) new drug application or abbreviated new drug application that purports to cover any riociguat product (“Riociguat Drug Application”); (ii) any correspondence with the FDA regarding any Riociguat Drug Application; (iii) drafts of items (i) or (ii) above; (iv) sensitive, and/or proprietary information pertaining to marketing, sales, revenues, or profits, or any scientific or technical information relating to the research and development of riociguat or to any existing products or products in development; and/or (v) any document attaching any of items (i)-(iv) of this ¶ 2.1. Consistent with this definition, documents previously produced by Defendants in this action bates numbered ALEMBIC\_RIO\_0000001–ALEMBIC\_RIO\_0030719, which were produced with the designation “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY,” are redesignated as CONFIDENTIAL INFORMATION under this Protective Order. The designation of “CONFIDENTIAL” or “CONFIDENTIAL INFORMATION” by a party or non-party who seeks to invoke protection under this Protective Order (“Producing Party”) constitutes its representation that it reasonably and in good faith believes that the designated material constitutes or contains information as described above.

2.2 As used herein, the terms “HIGHLY CONFIDENTIAL” and “HIGHLY CONFIDENTIAL INFORMATION” (which are used herein interchangeably and are synonymous with one another) if, and only if, that information is “CONFIDENTIAL” as set forth in or ¶ 2.1 above and constitutes or reflects highly sensitive financial or strategic commercial information,

including forward-looking forecasts and financial assumptions; and/or (ii) any document attaching any of item (i) of this ¶ 2.2.

2.3 CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, respectively, shall include: (a) all copies, extracts, and complete or partial summaries prepared from such CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION; (b) portions of deposition transcripts and exhibits thereto that contain, summarize, or reflect the content of any such CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION; (c) portions of briefs, memoranda, or any other writings filed with the Court and exhibits thereto that contain, summarize, or reflect the content of any such CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION; (d) written discovery responses, answers, and/or contentions that contain, summarize, or reflect the content of any such CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION; (e) deposition testimony designated in accordance with the paragraphs below; and (f) portions of expert reports and exhibits thereto that contain, summarize, or reflect the content of any such CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION.

2.4 In the event that a document produced in this action contains both HIGHLY CONFIDENTIAL INFORMATION and CONFIDENTIAL INFORMATION, but is designated HIGHLY CONFIDENTIAL in its entirety by the party that produced it, then any party receiving such document may request that the producing party provide a copy that has any HIGHLY CONFIDENTIAL INFORMATION redacted and therefore can be treated as containing CONFIDENTIAL INFORMATION. The request shall be in writing, and the producing party shall have three (3) business days from receipt of the request to produce such a redacted version.

2.5 In the event that a party marks a pleading, expert report, contention, correspondence, discovery request, discovery response, or material filed with the Court as containing HIGHLY CONFIDENTIAL INFORMATION because it contains a party's own HIGHLY CONFIDENTIAL INFORMATION, then that party shall, within two (2) business days, provide to the recipient(s) a version that has the designating party's own HIGHLY CONFIDENTIAL INFORMATION redacted.

### **3. Designation.**

Each party shall have the right to designate information as CONFIDENTIAL or HIGHLY CONFIDENTIAL, subject to this Protective Order. It shall be the duty of the Producing Party to give notice, in accordance with the provisions of this Protective Order, of the information designated to be covered by this Protective Order. To the extent that material is marked CONFIDENTIAL or HIGHLY CONFIDENTIAL, such material shall only be revealed to or used by limited categories of individuals, as provided for herein, and shall not be communicated in any manner, either directly or indirectly, to any person or entity not permitted disclosure pursuant to this Protective Order. Any copies of such material, abstracts, summaries or information derived therefrom, and any notes or other records regarding the contents thereof, shall also be deemed CONFIDENTIAL or HIGHLY CONFIDENTIAL accordingly, and the same terms regarding confidentiality of these materials shall apply as apply to the originals.

### **4. Marked Documents and Things.**

4.1 Each page of a document and each thing that constitutes or contains CONFIDENTIAL INFORMATION shall be labeled or marked with the legend "CONFIDENTIAL – PROTECTIVE ORDER MATERIAL" or "CONFIDENTIAL INFORMATION – PROTECTIVE ORDER MATERIAL" when the document or thing is

produced to the receiving parties. Likewise, each page of a document and each thing that constitutes or contains HIGHLY CONFIDENTIAL INFORMATION shall be labeled or marked with the legend “HIGHLY CONFIDENTIAL – PROTECTIVE ORDER MATERIAL” or “HIGHLY CONFIDENTIAL INFORMATION – PROTECTIVE ORDER MATERIAL” when the document or thing is produced to the receiving parties. Anything that cannot be so labeled or marked on its face shall be labeled or marked by placing the appropriate legend on a container or package in which it is produced or on a tag attached thereto. Material produced without any such legend clearly indicating that it is subject to this Protective Order shall not be subject to the protections afforded to such information under this Protective Order unless otherwise agreed by the parties, ordered by the Court, or designated in accordance with ¶ 17 of this Protective Order.

4.2 Should a party opt to make materials available for inspection in response to a discovery request, such inspection shall be conducted on an outside-counsel-eyes-only basis. Once produced, such materials shall be treated by the receiving parties in accordance with any confidentiality designation made at the time of their production.

4.3 Documents and things produced or made available for inspection may be subject to redaction, in good faith by the producing party, of information that is neither relevant to the subject of this litigation nor reasonably calculated to lead to the discovery of admissible evidence, or is subject to the attorney-client privilege or to work-product immunity. Each such redaction, regardless of size, shall be clearly labeled as redacted. Information involving the privacy interests of one or more individuals or subject to data privacy restrictions (such as social security numbers, dates of birth, private addresses or telephone numbers, or other personal information) can be redacted in accordance with the provisions of this paragraph. This paragraph shall not be construed as a waiver of any party’s right to seek disclosure of redacted information.

**5. Limit On Use And Disclosure Of Designated Information.**

5.1 The production of CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION by a party under the terms of this Protective Order shall not be construed to mean that the Producing Party has waived any objection to the production, relevancy or admissibility of such information. Nothing contained herein shall preclude any party from opposing any discovery on any basis. Further, nothing in this Protective Order constitutes an admission by any party that any specific item of CONFIDENTIAL INFORMATION and/or HIGHLY CONFIDENTIAL INFORMATION is a trade secret or otherwise confidential and proprietary to a party.

5.2 Each party and all persons bound by the terms of this Protective Order shall use any information or document designated CONFIDENTIAL or HIGHLY CONFIDENTIAL only in connection with the prosecution or defense of this action, except by consent of the parties or order of the Court. Such use includes, but is not limited to, offering evidence and testimony at trial and/or other hearings, preparing for and conducting discovery, preparing for trial, and supporting or opposing any motion in this action. Except as provided for in this Order, no party or other person shall disclose or release any information or document governed by this Protective Order to any person not authorized pursuant to this Protective Order to receive such information or document.

Material designated CONFIDENTIAL or HIGHLY CONFIDENTIAL, and all information derived therefrom, shall be used only by persons permitted access to such information under this Protective Order, shall not be disclosed by the receiving parties to any party or person not entitled under this Protective Order to have access to such material, and shall not be used by the receiving parties for any purpose other than in connection with this action, including without limitation for

any research, development, manufacture, patent prosecution, financial, commercial, marketing, regulatory, business, or other competitive purpose (except for settlement of the above-captioned case).

5.3 Absent consent of the producing parties and/or further order of this Court, all persons receiving information designated CONFIDENTIAL or HIGHLY CONFIDENTIAL under this Protective Order from an opposing party in this action are expressly prohibited from using or disclosing such information in connection with any practice before or communication with the United States Patent and Trademark Office or the Patent Trial and Appeal Board, the FDA (including Citizen Petitions), the United States Pharmacopoeia, or their counterpart organizations in any foreign jurisdiction, and are expressly prohibited from using or disclosing such information in connection with any other civil action.

5.4 Absent consent of the producing parties and/or further order of this Court, any person who receives information designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION under this Protective Order from, in the case of an individual representing or affiliated with a plaintiff, a defendant in this action, or in the case of an individual representing or affiliated with a defendant, a plaintiff in this action, shall not, thereafter during the course of this action and continuing for two years following final termination of this action, directly or indirectly work on or participate in (i) the drafting or editing of any patent application (foreign or domestic), claim, or claim amendment that is directed to any product containing riociguat, including without limitation the uses of any product containing riociguat or the method of manufacturing any product containing riociguat; or (ii) the drafting or editing of a Citizen Petition (or related submission, including a response to a Citizen Petition) concerning any product containing riociguat, including without limitation the uses of any product containing riociguat or



the method of manufacturing any product containing riociguat. For clarity, nothing in item (i) of this ¶ 5.4 shall prevent an individual who receives CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION from directly or indirectly working on or participating in (a) *inter partes* reviews, post grant reviews, or re-issue or re-examination proceedings at the U.S. Patent and Trademark Office or the Patent Trial and Appeal Board related to riociguat, or (b) pre- or post-grant opposition proceedings or invalidation request proceedings before a foreign patent office or court related to riociguat, so long as the individual does not directly or indirectly work on or participate in the drafting or editing of a claim or claim amendment as described in item (i). For further clarity, nothing in item (ii) of this ¶ 5.4 shall prevent an individual who receives CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION from directly or indirectly working on or participating in (a) the drafting or editing of submissions to the FDA that are not Citizen Petitions or related submissions, including but not limited to submissions related to the listing of a patent in the Orange Book, or (b) a Citizen Petition (or related submission, including a response to a Citizen Petition) concerning that individual's company's own riociguat product—*i.e.*, in the case of Bayer, a Citizen Petition involving Adempas® itself (or a method of using Adempas® or manufacturing Adempas®), or in the case of a defendant, a Citizen Petition involving that defendant's own generic riociguat products (or a method of using or manufacturing such generic riociguat products)—so long as such individual does not use CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION received from an opposing party in this action in connection with such Citizen Petition (or related submission).

5.5 If a party opts to produce documents containing CONFIDENTIAL or HIGHLY CONFIDENTIAL INFORMATION in hard copy, then any complete hard copy production sets

shall be maintained at the offices of outside counsel only. To be clear, although any individual documents produced containing HIGHLY CONFIDENTIAL INFORMATION should be maintained at the offices of outside counsel only, nothing in this Protective Order requires that individual documents containing CONFIDENTIAL INFORMATION be maintained at the offices of outside counsel.

5.6 It is understood that counsel for a party may give advice and opinions to his or her client based on his or her evaluation of designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION received by the party, provided that such rendering of advice and opinions shall not reveal the content of such information, other than in summary form, except by prior written agreement with counsel for the Producing Party.

5.7 The attorneys of record for the parties and other persons receiving information governed by this Protective Order shall exercise reasonable care to ensure that the information and documents governed by this Protective Order are (a) used only for the purposes specified herein, and (b) disclosed only to authorized persons.

5.8 The parties agree to meet and confer in good faith prior to trial to establish procedures concerning the use of CONFIDENTIAL and HIGHLY CONFIDENTIAL INFORMATION at trial. Nothing in this Protective Order shall preclude any party from moving the Court to seal the courtroom, trial exhibits, or the trial transcript in order to preserve the confidential nature of any CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION used at trial.

## **6. Disclosure Of CONFIDENTIAL INFORMATION.**

6.1 Every person to whom CONFIDENTIAL INFORMATION contained therein is to be disclosed, summarized, described, characterized, or otherwise communicated or made available

in whole or in part, first shall be advised that the material or information is being disclosed pursuant and subject to the terms of this Protective Order.

6.2 Except as provided in ¶¶ 12, 13, and 19, documents or information designated CONFIDENTIAL INFORMATION, as described in this Protective Order, shall be disclosed by the recipient thereof, on a need-to-know basis, only to:

(a) Up to three (3) in-house personnel employed by a Bayer entity, each of whom (i) is an attorney or counsel or, if not an attorney or counsel, is in the intellectual property or legal department/division of said entity; (ii) is responsible for overseeing this litigation, and (iii) does not currently have primary responsibility for patent prosecution in connection with riociguat. For clarity, while such an in-house person who does not currently have primary responsibility for patent prosecution in connection with riociguat may be a designated person under ¶ 6.2 (a), such person may not, commencing as of the date he or she receives information designated CONFIDENTIAL INFORMATION under this Protective Order from an opposing party in this action, and continuing for two years following final termination of this action, directly or indirectly work on or participate in the drafting or editing of any claims or claim amendments in connection with such patent prosecution. For further clarity, a designated in-house person may directly or indirectly work on and participate in, and have primary responsibility for, (1) *inter partes* reviews, post grant reviews, or re-issue or re-examination proceedings at the U.S. Patent Trademark Office or Patent Trial and Appeal Board related to riociguat; or (2) pre- or post-grant opposition proceedings or invalidation request proceedings before a foreign patent office or court related to riociguat, provided that such designated person does not, commencing as of the date he or she receives information designated CONFIDENTIAL INFORMATION under this Protective Order from an opposing party in this action, and continuing for two years following final termination of

this action, directly or indirectly work on or participate in the drafting or editing of any claims or claim amendments as part of any such proceeding. Such designated individuals shall execute a copy of the Confidentiality Undertaking attached hereto as Exhibit A, which shall in turn be provided to outside counsel for the other parties in this action, and may disclose CONFIDENTIAL INFORMATION to their secretarial, paralegal, clerical or legal assistant staff. In the event that one of the aforementioned in-house personnel ceases to have responsibilities relating to this litigation, a party may designate another in-house person who otherwise qualifies under the provisions of this ¶ 6.2 (a) to replace such person upon giving written notice of such change to outside counsel for the other parties in this action and providing an executed copy of the Confidentiality Undertaking;

(b) Up to three (3) in-house personnel employed by an Alembic entity, each of whom (i) is an attorney or counsel or, if not an attorney or counsel, is in the intellectual property or legal department/division of said entity, (ii) is responsible for overseeing this litigation, and (iii) does not currently have primary responsibility for patent prosecution in connection with riociguat. For clarity, while such an in-house person who does not currently have primary responsibility for patent prosecution in connection with riociguat may be a designated person under ¶ 6.2 (b), such person may not, commencing as of the date he or she receives information designated CONFIDENTIAL INFORMATION under this Protective Order from an opposing party in this action, and continuing for two years following final termination of this action, directly or indirectly work on or participate in the drafting or editing of any claims or claim amendments in connection with such patent prosecution. For further clarity, a designated in-house person may directly or indirectly work on and participate in, and have primary responsibility for, (1) *inter partes* reviews, post grant reviews, or re-issue or re-examination proceedings at the U.S. Patent and Trademark

Office or Patent Trial and Appeal Board related to riociguat; or (2) pre- or post-grant opposition proceedings or invalidation request proceedings before a foreign patent office or court related to riociguat, provided that, commencing as of the date he or she receives information designated CONFIDENTIAL INFORMATION under this Protective Order from an opposing party in this action, and continuing for two years following final termination of this action, such designated person does not directly or indirectly work on or participate in the drafting or editing of any claims or claim amendments as part of any such proceeding. Such designated individuals shall execute a copy of the Confidentiality Undertaking attached hereto as Exhibit A, which shall in turn be provided to outside counsel for the other parties in this action, and may disclose CONFIDENTIAL INFORMATION to their secretarial, paralegal, clerical or legal assistant staff. In the event that one of the aforementioned in-house personnel ceases to have responsibilities relating to this litigation, a party may designate another in-house person who otherwise qualifies under the provisions of this ¶ 6.2 (b) to replace such person upon giving written notice of such change to outside counsel for the other parties in this action and providing an executed copy of the Confidentiality Undertaking;

(c) outside trial counsel or outside attorneys of record for the parties, including, but not limited to, such attorneys' partners, associates, staff and contract attorneys, and their authorized secretarial, paralegal, clerical and legal assistant staff whose duties and responsibilities require access to material designated CONFIDENTIAL INFORMATION;

(d) the Court and Court personnel;

(e) witnesses or potential witnesses in this action and their counsel, to the extent that the witness at such proceeding is qualified under the terms of this Protective Order to have access to such designated material;

(f) outside consultants or experts and their staffs retained by the parties or their attorneys for purposes of this action, who are not objected to pursuant to ¶ 8, and who first agree to be bound by the terms of this Protective Order by executing a copy of the Undertaking attached hereto as Exhibit A;

(g) court reporters, videographers, and their respective staffs employed in connection with this action;

(h) non-parties specifically retained to assist outside counsel of record with copying and computer services necessary for document handling, storage, and other litigation support personnel (e.g., graphic designers and animators, database storage, organization, or retrieval vendors and their personnel); and

(i) any interpreter or translation service retained to assist outside counsel of record, and any typist or transcriber used thereby, who either first executes a copy of the Confidentiality Undertaking attached hereto as Exhibit A or has made suitable arrangements with the party that has retained such an individual to preserve the confidentiality of the CONFIDENTIAL INFORMATION.

**7. Disclosure Of HIGHLY CONFIDENTIAL INFORMATION.**

7.1 Every person to whom HIGHLY CONFIDENTIAL INFORMATION contained therein is to be disclosed, summarized, described, characterized, or otherwise communicated or made available in whole or in part, first shall be advised that the material or information is being disclosed pursuant and subject to the terms of this Protective Order.

7.2 Except as provided in ¶¶ 12, 13, and 19, documents or information designated HIGHLY CONFIDENTIAL INFORMATION, as described in this Protective Order, shall be disclosed by the recipient thereof, on a need-to-know basis, only to:

(a) outside trial counsel or outside attorneys of record for the parties, including, but not limited to, such attorneys' partners, associates, staff and contract attorneys, and their authorized secretarial, paralegal, clerical and legal assistant staff whose duties and responsibilities require access to material designated HIGHLY CONFIDENTIAL INFORMATION;

(b) outside consultants or experts and their staffs retained by the parties or their attorneys for purposes of this action, who are not objected to pursuant to ¶ 8, and who first agree to be bound by the terms of this Protective Order by executing a copy of the Undertaking attached hereto as Exhibit A;

(c) the Court and Court personnel;

(d) witnesses or potential witnesses in this action and their counsel, to the extent that the witness at such proceeding is qualified under the terms of this Protective Order to have access to such designated material;

(e) court reporters, videographers, and their respective staffs employed in connection with this action;

(f) non-parties specifically retained to assist outside counsel of record with copying and computer services necessary for document handling, storage, and other litigation support personnel (e.g., graphic designers and animators, database storage, organization, or retrieval vendors and their personnel); and

(g) any interpreter or translation service retained to assist outside counsel of record, and any typist or transcriber used thereby, who either first executes a copy of the Confidentiality Undertaking attached hereto as Exhibit A or has made suitable arrangements with the party that has retained such an individual to preserve the confidentiality of the HIGHLY CONFIDENTIAL INFORMATION.

## 8. Identification Of Experts And Consultants.

8.1 If any party desires to disclose information designated CONFIDENTIAL or HIGHLY CONFIDENTIAL to any expert or consultant pursuant to ¶¶ 6(f) and 7(b) above, it must first identify in writing (which can be by email or facsimile) to the attorneys for the Producing Party each such expert or consultant. Expert or consultant disclosures made under the parties' Access and Non-Disclosure Agreement dated May 2023 are deemed disclosed under this Protective Order.

8.2 The attorneys for the Producing Party shall have seven (7) business days from receipt of such notice to object in writing to disclosure of such information to any of the experts or consultants so identified. Any party that fails to object in writing within seven (7) business days of receiving such notice shall be deemed to have waived such objection and the parties shall be deemed to have agreed upon disclosure to the expert for purposes of ¶¶ 6.2 (f) and 7.2 (b). No CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION may be disclosed to any proposed expert or consultant until such time as the parties are deemed to have agreed upon disclosure to the expert for purposes of ¶¶ 6.2 (f) and 7.2 (b) pursuant to the provisions of ¶ 8.

8.3 The identification of an expert or consultant pursuant to ¶ 8.1 shall include the full name and professional address and/or affiliation of the proposed expert or consultant, an up-to-date curriculum vitae, any prior or current employments or consultancies for any party or other company in the pharmaceutical industry within the last five (5) years,<sup>1</sup> including a list of the cases

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<sup>1</sup> In the event that the expert or consultant is not able to provide the identity of a party or other company within the pharmaceutical industry due to confidentiality restrictions (such as a contractual requirement to maintain in confidence the identity of the party or other company within the pharmaceutical industry), the expert or consultant shall list "Confidential



in which the expert or consultant has testified at deposition, at a hearing, or at trial within the last four years, and an executed copy of the Confidentiality Undertaking attached hereto as Exhibit A.

8.4 The parties shall attempt to resolve any objections informally. Within five (5) business days of receipt of an objection, the parties shall meet and confer to attempt to resolve their dispute. If the objections cannot be resolved, the party opposing disclosure of the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION to the expert or consultant may raise the issue with the Court in accordance with the Court's procedures for resolution of discovery disputes. If the issue is raised with the Court, the party opposing disclosure shall bear the burden of proof with respect to the propriety of its objection and blocking of said individual from serving as an expert or consultant in this case. After meeting and conferring in an attempt to resolve the issue, any party that fails to raise such an issue with the Court within ten (10) business days of notifying a party of an objection to disclosure under ¶¶ 8.1 and 8.2 shall be deemed to have waived such objection and the parties shall be deemed to have agreed upon disclosure to the expert for purposes of ¶¶ 6.2(f) and 7.2(b).

## **9. Agreement Of Confidentiality.**

9.1 In no event shall any information designated CONFIDENTIAL or HIGHLY CONFIDENTIAL be disclosed to any person authorized pursuant to ¶¶ 6.2(f) and 7.2(b) until such person has executed a written Confidentiality Undertaking (in the form set forth in Exhibit A hereto) acknowledging and agreeing to be bound by the terms of this Protective Order. Counsel for the party seeking to disclose material designated under this Order to any such person pursuant

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Consultancy/Employment" on his or her curriculum vitae. The parties shall thereafter meet and confer concerning such disclosure, and if they are unable to resolve any objections concerning the disclosure, shall proceed in accordance with the provisions of Section 8.4.

to this paragraph shall be responsible for retaining the executed originals of all such Confidentiality Undertakings.

9.2 Any vendor described in ¶ 6(h) or ¶ 7(f) that is accessing hard copies of CONFIDENTIAL or HIGHLY CONFIDENTIAL INFORMATION on behalf of a party shall return to the party's counsel all hard copies of such documents as soon as the information has been encoded and loaded into the computer, copied, prepared or otherwise processed by the vendor.

**10. Related Documents.**

10.1 The restrictions contained herein to the use of information designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION shall apply to (a) portions of documents, copies, extracts, and complete or partial summaries prepared from or containing such information; (b) portions of deposition transcripts and exhibits thereto which contain or reflect the content of any such documents, copies, extracts, or summaries; (c) subject to the provisions of ¶ 14, portions of briefs, memoranda or any other papers filed with the Court and exhibits thereto or expert reports which contain or reflect the content of any such documents, copies, extracts, or summaries; (d) deposition testimony designated in accordance with ¶ 11; (e) testimony taken at a hearing or other proceeding and designated in accordance with ¶ 22; and/or (f) portions of expert reports and exhibits thereto that contain, summarize, or reflect the content of any such CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION.

**11. Designation Of Deposition Transcripts.**

11.1 Portions of deposition transcripts containing CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION may be designated as subject to this Protective Order either on the record during the deposition or by providing written notice within thirty-five (35) days following receipt of the official transcript of the deposition to the reporter and all counsel

of record of the specific pages and lines that contain CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, in which case all counsel receiving such notice shall mark the copies or portions of the designated transcript in their possession or under their control as directed by the designating party.

11.2 All deposition transcripts not previously designated shall be deemed to be, and shall be treated as CONFIDENTIAL for a period of thirty-five (35) days after receipt of the official transcript of the deposition, and the transcript shall not be disclosed during such time to persons other than those persons qualified to receive such information pursuant to this Protective Order.

11.3 The Producing Party shall have the right to exclude from portions of a deposition, before the taking of testimony which the Producing Party designates CONFIDENTIAL or HIGHLY CONFIDENTIAL and subject to this Protective Order, all persons other than those persons previously qualified to receive such information pursuant to this Protective Order. In-house counsel authorized to receive CONFIDENTIAL INFORMATION but not HIGHLY CONFIDENTIAL INFORMATION in accordance with the provisions of ¶ 6 and ¶ 7 shall only be excluded from the portion of the deposition that contains questions and answers that reveal the content of information designated HIGHLY CONFIDENTIAL. If such individuals fail to comply with such a request, the requesting counsel for the Producing Party may seek relief from the Court pursuant to the Court's procedures for resolution of discovery disputes, and pending resolution of that request, instruct or request the witness not to answer questions relating to, or to limit disclosure of, the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION at issue.

**12. Disclosure to Other Individuals.**

Notwithstanding any other provision of this Protective Order, CONFIDENTIAL INFORMATION and HIGHLY CONFIDENTIAL INFORMATION may be disclosed to the following persons, irrespective of whether they are identified in ¶ 6 or ¶ 7, as follows:

12.1 CONFIDENTIAL INFORMATION and HIGHLY CONFIDENTIAL INFORMATION may be disclosed to persons not identified in ¶ 6 or ¶ 7 as agreed by the producing parties by written consent.

12.2 Any receiving party may move the Court (in accordance with the Court's procedures for resolution of discovery disputes) for an Order that a person not identified in ¶ 6 or ¶ 7 be given access to information designated CONFIDENTIAL or HIGHLY CONFIDENTIAL. If the motion is granted, such person may have access to the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION after first signing the Confidentiality Undertaking set forth in Exhibit A.

12.3 Nothing in this Protective Order shall prohibit counsel or a party from disclosing a document containing information designated CONFIDENTIAL or HIGHLY CONFIDENTIAL at deposition, at trial, or at any other court hearing, to: (i) any person who appears from the face of the document to have drafted, prepared, executed, had knowledge of the substance of, or received the document, or any person who is reasonably likely to have had prior lawful access to the document or the information contained therein; or (ii) a currently employed officer, employee, or expert of the party that produced the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION.

**13. Confidentiality Of Party's Own Documents and Information.**

Nothing herein shall affect the right of the Producing Party to disclose to its officers, directors, employees, attorneys, consultants or experts, or to any other person, its own information. Such disclosure shall not waive the protections of this Protective Order and shall not entitle other parties or their attorneys to disclose such information in violation of it, unless by such disclosure of the Producing Party the information becomes public knowledge. Similarly, the Protective Order shall not preclude a party from showing its own information to its officers, directors, employees, attorneys, consultants or experts, or to any other person, which information has been filed under seal by the opposing party.

**14. Filing Designated Information With The Court.**

Any information designated CONFIDENTIAL or HIGHLY CONFIDENTIAL, if filed with the Court, shall be filed under seal pursuant to the Court's procedures for filing materials under seal, and shall be made available only to the Court and to persons authorized by the terms of this Protective Order.

**15. Other Protections.**

15.1 No receiving party shall use any CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, or information derived therefrom, for purposes other than the prosecution or defense of this action, including, without limitation, for purposes of preparing, filing or prosecuting any patent application, continuation or divisional patent application, reissue patent application or request for re-examination.

15.2 Any party may mark any document or thing containing CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION as an exhibit to a deposition,

hearing, or other proceeding, provided the witness at such proceeding is qualified under the terms of this Protective Order to have access to such designated material.

**16. Challenge to Confidentiality.**

16.1 This Protective Order shall not preclude any party from seeking and obtaining, on an appropriate showing, such additional protection with respect to the confidentiality of documents or other discovery materials as that party may consider appropriate. Nor shall any party be precluded from (a) claiming that any matter designated hereunder is not entitled to the protections of this Protective Order, (b) applying to the Court for an order permitting the disclosure or use of information or documents otherwise prohibited by this Protective Order, or (c) applying for a further order modifying this Protective Order in any respect. No party shall be obligated to challenge the propriety of any designation, and failure to do so shall not preclude a subsequent challenge to the propriety of such designation.

16.2 On any challenge to the designation of any information, the burden of proof shall lie with the Producing Party to establish that the information is, in fact, CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION. If a party seeks declassification or removal of particular items from this designation on the ground that such designation is not necessary to protect the interests of the Producing Party, the following procedure shall be utilized:

(a) The party seeking such declassification or removal shall give counsel of record for the other party written notice thereof, specifying the designated information as to which such removal is sought and the reasons for the request;

(b) The parties shall then meet and confer within five (5) business days after receipt of the notification to attempt to resolve the dispute without the involvement of the Court; and

(c) If, after conferring, the parties cannot reach agreement concerning the matter within seven (7) business days after the delivery and receipt of the notice, then the party requesting the declassification or removal of particular items may challenge the designation in accordance with the Court's procedures for resolution of discovery disputes.

**17. Inadvertent Failure To Designate.**

17.1 Notwithstanding the obligation to timely designate CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION under the foregoing paragraphs, the inadvertent or unintentional failure to designate specific information as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION shall not be deemed a waiver in whole or in part of the claim of confidentiality. A Producing Party or non-party that inadvertently fails to designate as CONFIDENTIAL or HIGHLY CONFIDENTIAL an item pursuant to this Protective Order at the time of production may thereafter make a designation pursuant to this Protective Order by serving notice thereof in writing, accompanied by substitute copies of each item, appropriately designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL. Upon receipt of such notice and properly marked material, the receiving parties shall treat such information consistent with the redesignation. All copies of the misdesignated documents shall be promptly destroyed or returned to the Producing Party, and any memoranda or work product derived therefrom shall thereafter be treated as containing CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION.

17.2 Should any CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION be disclosed, through inadvertence or otherwise, by the receiving party to any person or party not authorized under this Protective Order, then the receiving party shall (a) use its best efforts to obtain the return of any such material or information and to bind such person to the

terms of this Protective Order; (b) within three (3) business days of the discovery of such disclosure, inform such person of all provisions of this Protective Order and request such person to sign the Confidentiality Undertaking in the form attached hereto as Exhibit A; and (c) within five (5) business days of the discovery of such disclosure, inform the Producing Party of all pertinent facts relating to such disclosure, including the identity of such person and the information disclosed. The responsible party also promptly shall take all reasonable measures to ensure that no further or greater unauthorized disclosure or use of such material is made and to retrieve any material improperly disclosed. Each party shall cooperate in good faith in that effort. No party shall be held in breach of this Protective Order if, prior to notification of such later designation, such CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION had been disclosed or used in a manner inconsistent with such later designation.

**18. Inadvertent Production or Disclosure of Privileged Materials.**

18.1 Pursuant to Federal Rule of Evidence 502, the inadvertent production or disclosure of any document or thing (including information) otherwise protected by the attorney-client privilege, work-product immunity, or other privilege or immunity shall not operate as a waiver of any such privilege or immunity if, after recognizing that privileged information has been produced or disclosed, the party who made the inadvertent production or disclosure sends to each receiving party a written request for return of the inadvertently produced or disclosed document or thing within a reasonably prompt period of time after recognizing that the privileged information has been produced or disclosed. Within ten (10) days of receiving such a request, the receiving party shall (a) return to the producing party all such documents and things identified by the producing party as being protected by the attorney-client privilege, work-product immunity, or other privilege or immunity and as having been inadvertently produced, and (b) delete any electronic records



thereof (with the exception of back-up tapes or other archival media, which should be treated in accordance with standard retention policies, *i.e.*, which are not retained indefinitely without being overwritten). The receiving party shall not utilize the information contained in the inadvertently produced documents or things for any purpose, or disseminate or transmit such information, except as provided in subparagraph ¶ 18.2 below.

18.2 If the receiving party wishes to contest that any such document or thing is protected by the attorney-client privilege or by work-product immunity, the receiving party shall so notify the Producing Party in writing when the document or thing is destroyed or returned to the Producing Party (“Notice of Designation”). The receiving party may retain one (1) copy of the document(s) or thing(s) at issue for the purposes of filing a motion to contest the designation. The copy retained by the receiving party must be sequestered, and may not be used for any purpose except to present the information to the Court for a determination of the claim of privilege.

18.3 Within five (5) days after receiving a Notice of Designation, the Producing Party shall provide to the receiving party for each such document or thing a description of the basis for the claim of privilege or immunity.

18.4 Within five (5) days after receiving such description, the receiving party may seek relief from the Court to compel production of such documents and things, the protection of which is still disputed, in accordance with the Court’s procedures for resolution of discovery disputes. If resolution is not sought from the Court within such five (5)-day period, the one (1) copy, if any, retained by the receiving party as set forth in ¶ 18.2 shall be immediately returned to the Producing Party. Likewise, in the event that the Court rejects the receiving party’s challenge to the privileged status of the inadvertent production, the one (1) copy, if any, retained by the

receiving party as set forth in ¶ 18(a) shall be immediately destroyed or returned to the Producing Party.

18.5 With respect to documents and things subsequently generated by a receiving party, which documents and things contain information derived from such inadvertently produced documents and things, if the receiving party does not notify the Producing Party that the receiving party disputes the claims of attorney-client privilege or work-product immunity, or if the Court rejects any challenge by the receiving party to the privileged status of the inadvertent production, the receiving party shall either destroy the derivative documents and things or redact from them all such derivative privileged or work-product information in a manner such that the derivative information cannot in any way be retrieved or reproduced (with the exception of derivative information stored on back-up tapes or other archival media, which should be treated in accordance with standard retention policies, *i.e.*, which are not retained indefinitely without being overwritten).

18.6 The procedures set forth in this ¶ 18 for challenging the privileged status of an inadvertent production shall not result in any waiver of the attorney-client privilege, the work product immunity, or any other privilege or immunity.

18.7 The facts or circumstances of the inadvertent production shall in no way be relied upon as a ground to support any argument that the information is no longer subject to any applicable privilege or immunity. For purposes of this section, it shall be irrelevant which party initially discovers the inadvertently or mistakenly produced items that are otherwise properly subject to a claim of attorney-client privilege, work product immunity, or on any other protection from discovery.

## **19. Limitations Of Protective Order**

19.1 This Protective Order shall not apply to information that is or was available to the public prior to disclosure. The restrictions contained in this Protective Order shall not apply to information that is, was, or became available to the public other than by an act or omission of the party to whom such disclosure is made, or that is legitimately and independently acquired from a source not subject to this Protective Order. Specifically, this includes information a party receives at a later date from a third party properly and rightfully in possession of said information, and not as a result of any breach of confidentiality, and properly and rightfully authorized to make disclosure without restriction as to disclosure.

19.2 This Protective Order shall not apply to and, thus, does not restrict any party's use, for any purpose, of its own CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, or a party's use for any purpose of documents or other information that such party lawfully obtained prior to the entry of this Protective Order (unless subject to New Jersey Local Rule 5.3). Moreover, this Order shall not apply to and does not restrict any individual from reviewing or seeing any document authored, in whole or in part, by that individual.

19.3 This Protective Order is not intended to address discovery objections to produce, answer, or respond on the grounds of attorney-client privilege or work-product immunity, or to preclude either party from seeking further relief or protective orders from the Court as may be appropriate under the Federal Rules of Civil Procedure or the Local Rules of the District of New Jersey.

## **20. Other Proceedings.**

By entering this Order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this Order who becomes subject to a

motion to disclose another party's information designated CONFIDENTIAL or HIGHLY CONFIDENTIAL pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

**21. Non-Party Material.**

The terms of this Protective Order, as well as the terms of any protective order that may be entered into between a discovering party and third party for the production of information to the discovering party, are applicable to CONFIDENTIAL INFORMATION and HIGHLY CONFIDENTIAL INFORMATION provided by a nonparty. Information provided by a non-party in connection with this action and designated CONFIDENTIAL or HIGHLY CONFIDENTIAL accordingly, pursuant to the terms of this Protective Order shall be protected by the remedies and relief provided by this Protective Order.

**22. Designation of Hearing Testimony or Argument.**

With respect to testimony elicited during hearings and other proceedings, whenever counsel for any party deems that any question or line of questioning calls for the disclosure of CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, counsel may designate on the record prior to such disclosure that the disclosure is subject to confidentiality restrictions. Whenever matter designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION is to be discussed in a hearing or other proceeding, any party claiming such confidentiality may ask the Court to have excluded from the hearing or other proceeding any person who is not entitled under this Order to receive information so designated. Further, nothing in this Protective Order shall preclude any party

from moving the Court to seal the courtroom, exhibits, or the transcript in order to preserve the confidential nature of any information so designated.

**23. Final Termination of this Litigation.**

Within ninety (90) days following final termination of this litigation, including all appeals therefrom, unless otherwise agreed to in writing by an attorney of record for the designating party, each party shall assemble and return, or destroy and certify destruction of, all materials containing information designated CONFIDENTIAL or HIGHLY CONFIDENTIAL, including all copies, extracts and summaries thereof, to the party from whom the designated material was obtained, except that a party is not obligated to return or destroy CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION that may be contained on electronic backup back-up tapes or other archival media, which should be treated in accordance with standard retention policies, *i.e.*, which are not retained indefinitely without being overwritten. Notwithstanding the foregoing or a successful challenge under ¶ 16, and subject to a continuing obligation to protect all such material pursuant to this order, outside counsel may retain any archive copies of any filings, court papers, correspondence, deposition and trial transcripts, deposition and trial exhibits, expert reports, written discovery responses, and attorney work product (regardless of whether such materials contain or reference CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION for archival records).

**24. Waiver Or Termination Of Order.**

No part of the restrictions imposed by this Protective Order may be waived or terminated, except by written stipulation executed by counsel of record for the Producing Party, or by an order of the Court for good cause shown. The restrictions provided for herein shall not terminate upon the conclusion of this action, but shall continue until further Order of this Court.

In the event any party ceases to be engaged in the conduct of this action prior to the final termination of the litigation, such party's access to CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION shall be terminated, and all copies thereof shall be returned or destroyed in accordance with the terms of ¶ 23.

The provisions of this Order shall remain in full force and effect as to any person or party who previously had access to CONFIDENTIAL and/or HIGHLY CONFIDENTIAL material, except as may be specifically ordered by the Court or consented to by the Producing Party. For example, the termination of employment of any person with access to any CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION shall not relieve such person from the obligation of maintaining the confidentiality of such information.

**25. Modification Of Order; Prior Agreements.**

This Protective Order may be modified, and any matter related to it may be resolved, by written stipulation of the parties without further order of the Court. This Protective Order supersedes any agreements between the parties regarding the confidentiality of particular information entered into before the date of this Protective Order.

**26. Section Captions.**

The title captions for each section of this Protective Order are for convenience only and are not intended to affect or alter the text of the sections or the substance of the Order.

**27. Days.**

All references to "days" in this Order shall be construed as calendar days, unless otherwise specifically indicated.

**28. Order Applicable Upon Filing with the Court.**

Upon filing this Protective Order with the Court, the parties agree to treat it as "So Ordered," subject to any future modifications by agreement of the parties or by the Court.

s/Charles H. Chevalier

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Holding SA, and Alembic Pharmaceuticals,  
Inc.*

SO ORDERED:



UNITED STATES MAGISTRATE JUDGE

*James B. Clark, III*

DATE: 10/11/23

**EXHIBIT A**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

ADVERIO PHARMA GMBH, BAYER  
AG, and BAYER HEALTHCARE  
PHARMACEUTICALS INC.,

Plaintiffs,

v.

ALEMBIC PHARMACEUTICALS  
LIMITED, ALEMBIC GLOBAL  
HOLDING SA, and ALEMBIC  
PHARMACEUTICALS, INC.,

Defendants.

C.A. No. 2:23-cv-01285-ES-JBC

C.A. No. 2:22-cv-06104-ES-JBC

**DECLARATION AND CONFIDENTIALITY UNDERTAKING**

I certify that I have received and carefully read the Stipulated Protective Order (“Order”) in this action and that I fully understand the terms of the Order. I recognize that I am bound by the terms of the Order, and I agree to comply with those terms. I hereby consent to the personal jurisdiction of the United States District Court for the District of New Jersey for any proceedings involving the enforcement of the Order. I declare under penalty of perjury under the laws of the United States of America this Declaration and Confidentiality Undertaking is true and correct.

EXECUTED this \_\_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_.

\_\_\_\_\_  
Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Present Employer or Other Business Affiliation

\_\_\_\_\_  
Business Address